EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 212-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL WAVE 8 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

*****VOLUME I*****

DEPOSITION OF: OZ HARMANLI, M.D.

DATE: OCTOBER 3, 2018

HELD AT: NEW HAVEN LEGAL
900 CHAPEL STREET
NEW HAVEN, CT

Reporter: Samantha M. Howell, LSR #00462

APPEARANCES:

REPRESENTING THE PLAINTIFFS:

Wagstaff & Cartmell, LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
(816) 701-1100
By: Andrew N. Faes, Esquire

REPRESENTING THE DEFENDANT:

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(601) 985-4596
By: Paul S. Rosenblatt, Esquire

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PLAINTIFF'S EXHIBITS
(for identification)

STIPULATIONS

IT IS HEREBY STIPULATED AND AGREED by and between counsel for the respective parties hereto that all technicalities as to proof of the official character before whom the deposition is to be taken are waived.

IT IS FURTHER STIPULATED AND AGREED by and between counsel for the respective parties hereto that the reading and signing of the deposition by the deponent are required.

IT IS FURTHER STIPULATED AND AGREED by and between counsel for the respective parties hereto that all objections, except as to form, are reserved to the time of trial.

* * * * *

(Plaintiff's Exhibit 1, Notice of Deposition, marked for identification.)
(Plaintiff's Exhibit 2, Report, marked for identification.)
(Plaintiff's Exhibit 3, 1st Reliance List, marked for identification.)
(Plaintiff's Exhibit 4, 2nd Reliance List, marked for identification.)
(Plaintiff's Exhibit 5, CV, marked for identification.)
(Plaintiff's Exhibit 6, Invoice, marked for identification.)
(Deposition commenced: 2:04 p.m.)
Oz Harmanli, M.D., called as a witness, having been first duly sworn by Samantha Howell, a Notary Public in and for the State of Connecticut, was examined and testified as follows:

DIRECT EXAMINATION BY
MR. FAES:

Q Good afternoon, Dr. Harmanli. Did I get it right?
A Harmanli.
Q Harmanli?
A You got it, or you can say Harmanli like I used to go through, yes.

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Q Okay. My name is Andy Faes and I represent the plaintiffs in the litigation and I'm here today to take your deposition regarding the TVT and TVT-O case; you understand that?
A Yes.
Q Have you ever been deposed before, Doctor?
A Yes.
Q Have you ever been deposed as an expert before?
A Yes.
Q Okay. Have you ever been deposed as an expert in mesh litigation before?
A No.
Q Okay. So this will be your first time on being deposed as an expert for Ethicon and Johnson & Johnson?
A That is correct.
Q So you never testified as an expert for them before in any other litigation; is that true?
A No, I have not.
Q All right. And you stated -- about how many times have you been deposed before?
A Approximately seven.
Q And you testified that you -- strike that.
You said that you had testified as an expert witness before. How many times have you testified as an expert witness?

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A One time.
Q And that was in a deposition?
A That was in a deposition.
Q And did you end up testifying at trial in that case?
A Not yet.
Q Okay. And what case was that where you testified in a deposition?
A It was a litigation in Florida.
Q I'm sorry?
A It's a case from Florida. You need more details?
Q Yes. What kind of case, what was it?
A It is a medical malpractice case in Florida.
Q And are you -- did you testify on behalf of the plaintiff or the defendant in that case?
A It's a different kind of case that actually the patient, the defendant is -- is another law firm which did not act upon the appropriate rules and regulations in favor of the person who was injured in a medical malpractice. And then another -- and this person is now suing this malpractice lawyer in that case.
Q So it's a --
A I am --
Q Sorry, go on.
A I am basically representing the patient against

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the medical liability attorneys.
Q So it's a -- essentially a legal malpractice case?
A It's a legal malpractice case; perfect.
Q And you're representing -- strike that.
You don't represent anybody, but you're testifying on behalf of the firm that's being sued, or the firm that's bringing the suit.
A I'm representing the firm which is bringing the suit.
Q Okay. And what's the name of the firm that retained you in that case?
A St. Denis.
Q And you said that's a case down in Florida?
A Yes.
Q And you know whether that's a --
A Sarasota, Florida.
Q Okay. And do you know if that's in state court or in federal court?
A It's in state court.
Q And your testimony, was it given here in New Haven for your deposition or did you go down there?
A Correct, here.
Q And you stated in your -- I think it's in your export report, it says that you've prepared testimony

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before in mesh cases but haven't actually testified; is that a correct statement or not?
A So in mesh cases everything I prepared was really for Ethicon case.
Q So I've marked what's Exhibit Number 1 to your deposition, which is the notice of deposition in front of you. And that notice asks that you bring certain things to the deposition. And I believe either you or your counsel did bring a couple things. I've got a invoice, which we've marked as Exhibit Number 6, and a flash drive?
A Correct.
Q And is that all you brought here today in response to the document request in this notice?
A If this is the only invoice, I would -- Paul is bringing, and I had two others.
MR. ROSENBLATT: It's just for your general...
THE WITNESS: Oh, I see. Okay, yeah.
MR. ROSENBLATT: Yeah, just general.
THE WITNESS: Okay, thank you.
Q (By Mr. Faes) Okay. So this invoice that's marked a Exhibit Number 6 represents all of the work that you had done through May 14th of 2018 in producing your general TVT and TVT-O report, which is marked as -- what did I mark that as?

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A Six.
Q No, no, no, the report I didn't mark as six. So let me just ask that again. This invoice marked as Exhibit Number 6 represents all of the work you've done prior to May 14th in producing your TVT and TVT-O general expert report, which is marked as Exhibit Number 2; correct?
A That is correct.
Q And this invoice is dated May 14th, and your expert report is dated August 9th of 2018. Was there additional work that you've done between May 14th and August 9th that is not reflected in this invoice in preparing your general expert report?
A Probably was not finalized. I did not sign it maybe until then, but I did not do additional work specific to the general report.
Q And Exhibit Number 3 is your reliance list in this case. And Exhibit Number 4 is a supplemental reliance list that was updated within the last week; right?
A Correct.
Q So have you reviewed new materials in the last week to -- in order to update your reliance materials?
A No.
Q So let me ask you something about your reliance list marked as Exhibit Number 3 and Number 4. Did you make those lists or did someone make them for you?

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A Paul's firm helped me create that list.
Q And is that all the material that you reviewed and relied upon for your opinions as expressed in your TVT and TVT-O report marked as Exhibit Number 2?
A Yes.
Q Have you reviewed all of the materials in Exhibit Number 4, which is your supplemental reliance list?
A Yes, I did.
Q So in your -- in your invoice marked as Exhibit Number 6, you've got -- you've got various itemized things here that break out the work you've done. You've got 5 hours for review of deposition, 6 hours for review of cases, 12 hours for review of the literature and 22 hours for preparation of the general report; right?
A Correct.
Q There's also a number of internal documents and a number of plaintiff's expert reports that are in your supplemental reliance list; right?
A Correct.
Q How many hours -- first of all, how many hours would you say you've spent reviewing all of the expert reports that are on the last page of your supplemental reliance list?
A I would say six to eight hours, I'm assuming.
Q And is that six to eight hours included in this

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invoice marked as Exhibit Number 6, and, if so, where?
A It is likely anywhere between the review of the literature part and partly it's under preparation of the general report part.
Q Now, when you reviewed these expert reports, and it looks like there's well over 20 of them, did you review just the report itself or did you also review all of the materials that these experts relied on in coming to their conclusions?
A I tried to look at everything I could see. I did look at exhibits as well.
Q And I also see that there's a number of reports on here that you reviewed that aren't specific to the TVT and the TVT-O. For instance, you reviewed some Prolift reports and Prosima general reports; is that correct?
A Some of them as well.
Q Is there any particular reason why you chose to review those expert reports and not just the TVT and TVT-O?
A Because they are products of the same company which makes TVT and TVT-O, it just makes sense to make sure that I cover all the basis.
Q And on -- I think it's the third to last page, there's a page labeled company witness depositions, and it looks like there's only two of them; one day of Dr. Pete

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Newell and one day of Dr. Marty Wiseberg; do you see that?
A Yes.
Q Are those the only two depositions -- Ethicon depositions of company witnesses that you reviewed in coming to your conclusions in this case?
A Right.
Q And just those two days?
A As far as I remember, yes. And if they are listed that way, then it is true.
Q Okay. So I can turn your attention briefly to Exhibit Number 2, it's your TVT and TVT-O expert report; right?
A Correct.
Q When were you first contacted to be a expert for Ethicon and Johnson & Johnson on the TVT and TVT-O products?
A Last spring.
Q So not this year, but spring of 2017 or spring of 2018?
A Spring of 2018.
Q Spring of this year. So now in your report you go through various facts and discuss various facts. Did you discuss the facts that you felt were most important to you in drawing your conclusions in the report?

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A Yes.
Q And you also cite a lot of articles, a whole lot more than I've seen with other experts, throughout your report. In terms of your decision-making, why did choose that particular articles to cite in your expert report?
A I value literature highly. I believe whatever conclusion you should make in practice must come from high quality data. And I am obsessed to follow literature really well. So I want to make sure that everybody understands that whatever I'm saying is relying on the best evidence.
Q Now, before you were approached as a litigation expert to become a -- strike that.
Before you were approached to become a litigation expert for Ethicon and Johnson & Johnson regarding their mesh products, you'd actually worked for Ethicon as a consultant before that; right?
A I have worked for Ethicon as a consultant a few times in the past, yes.
Q When were you first -- when did you -- strike that.
When did you first become a consultant for Ethicon?
A I don't remember the year, but it has been at least ten years, so -- and maybe once or twice I was

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invited to their advisory meetings where they consult opinion leaders in our field, but it's been at least ten years.
Q So it's fair to say it's been at least since 2008 when you first became a consultant for Ethicon and Johnson & Johnson; right?
A I would suppose so.
Q Okay. And you've also worked as a consultant for a number of other pharmaceutical and medical device manufacturers; right?
A I've been asked to give my opinion on the devices and medical procedures they were innovating over the years, yes.
Q And one of the companies that you've done consulting work for is Coloplast; right?
A Coloplast, I've been in their various studies, yes.
Q And you've received money in the past on behalf of -- well, first of all, let me follow up with that. Coloplast is also a manufacturer of pelvic mesh devices, such as the slings and pelvic organ prolapse; correct?
A That is correct.
Q And, in fact, you are or have been an investigator on studies of two of their devices; right?
A That is right. I've been PI on two of their

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projects.
Q And one of the products that you've been a investigator for is the Altis sling; right?
A In that study I was on the arm which was not using Altis.
Q Okay. So you were on the control arm?
A That's correct.
Q And what was the control product for the Altis?
A Control product was transobturator slings.
Q And was the control arm a specific kind of obturator sling, or was it kind of a potpourri of obturator slings?
A It's been almost two years since we did that. I believe it was any transobturator outside-in sling would be fine.
Q And you've also served as an investigator for Coloplasts for the Restorelle product?
A Correct.
Q And is that trial still ongoing or have you completed that work?
A That is their 532 study postmarked analysis; I think they're wrapping it up now.
Q But you're done -- are you done enrolling patients for that study?
A We stopped enrolling.

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Q When did you stop enrolling patients for that study?
A I was a PI at my previous institution, which was Bay State Medical Center, and I moved to Yale University and there was already a PI here. My colleague, Dr. Bercik, and I just joined him and became like a sub-investigator for the site. So we stopped enrolling this past month.
Q Okay. And why did you stop enrolling this past month?
A Study was finished.
Q Okay. And do you have any plans to publish any results from that study?
A I am positive they will do that work, but I'm not sure if I'm going to be part of it.
Q Okay. And are you still using the Restorelle product outside of the study?
A Yes.
Q Are there -- and that's for -- you're using that for pelvic organ prolapse; right?
A Correct.
Q Are there any other meshes that you're currently using for the repair of pelvic organ prolapse?
MR. ROSENBLATT: Object to form. You can answer.
THE WITNESS: Currently I am using

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synthetic implants for sacrocolpopexy, and occasionally transvaginally for anterior and posterior repairs, and I use Restorelle for that.

Q (By Mr. Faes) So it's correct to say that currently the only mesh that you're using for pelvic organ repair is the Restorelle mesh; correct?

MR. ROSENBLATT: Object to form. Misstates.

THE WITNESS: I am quite positive that is true.

Q (By Mr. Faes) Okay. And you're saying that you -- not only do you use it for ASC or sacrocolpopexy, you do occasionally implant it transvaginally?

A That is correct.

Q Are there any -- well, strike that. I'm not going to get into that.

As you sit here today, have you asked to be an expert on any of Ethicon's pelvic floor products, such as Prolift or Prolift+M or Prosima?

A Yes.

Q You have been asked, but as you sit here today, you don't have any opinions to offer on the Prolift, Prosima devices; right?

MR. ROSENBLATT: Objection to form. He does not have a pelvic organ prolapse general report. And

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he's here today on his TVT, TVT-O general report.

MR. FAES: I understand that.

Q (By Mr. Faes) But as you sit here today, you don't intend to offer any opinions today -- I understand that might change -- on the Prosima, Prolift or Prolift+M device; right?

A Correct. And I got ready, prepared to speak on TVT and TVT-O today.

Q Okay. And so let me ask you this: What slings do you currently use for the treatment of SUI, stress urinary incontinence?

A Currently I use approximately 50/50 retropubic bottom-up TVT or outside-in transobturator sling from Boston Scientific, named Obtryx II.

Q And what's the retropubic bottom-up product that you use; is that the Advantage?

A Classic TVT.

Q Okay. So you use actually the Ethicon TVT?

A Ethicon Classic, the most original TVT.

Q So currently in your practice you're doing -- if I understand you correctly, you're doing about 50 percent Ethicon TVT for retropubic approaches, and 50 percent Boston Scientific Obtryx II for obturator approaches; correct?

A Correct.

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Q So you would agree with me at least currently you're not regularly using the Ethicon TVT-O in your practice; right?

MR. ROSENBLATT: Object to form.

THE WITNESS: I want to make sure I use both products because I'm a teacher, and I see them equally effective for most patients because I'm responsible in the teaching of the residents and fellows, I want to make sure that those skills are developed well.

Q (By Mr. Faes) But right now in your current practice, if you're going to implant a TVT -- strike that.

Right now currently in your practice, if you're going to implant an obturator sling, would it be fair to say that currently your sling of choice is the Obtryx II?

A That is because Boston Scientific probably made the right purchasing agreements with the hospital, and it is the most suitable -- economically suitable device to be used for that purpose.

Q So the answer to my question is yes, with that explanation; right?

A Correct.

Q Okay. And with regard to the Ethicon TVT product, are you using the mechanically cut mesh, or the laser cut mesh, or do you know?

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A I don't even pay attention to it.

Q So it's correct to say you couldn't tell me one way or the other if you regularly implant the mechanically cut mesh or the laser cut retropubic TVT when you implant?

A I think it's irrelevant.

Q I understand you think it's irrelevant, but my question is: Is it true that currently you can't tell me whether or not what you're implanting is mechanically cut or laser cut?

A What I'm hearing is Ethicon sometimes does it mechanically, sometimes laser when it comes down to cutting the product. So, to me, it really doesn't make any difference, so I never question that.

Q Do you know -- if you pick a TVT retropubic off the shelf, do you know how to even tell whether or not it's a mechanically cut or a laser cut?

A I do not.

Q Okay. Have you ever used the TVT Exact product?

A I have tried most of the full sling products and many of the single incision slings, but I have concluded that I can depend on the original TVT with its design. It's a marvelous innovative device that I just go back to that, because it also is backed by the largest evidence

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ever occurs for any medical device.
Q So it's correct to say that you've tried the TVT Exact before, but you simply prefer the original TVT retropubic?
A I believe it's a lot easier to teach the original design of TVT. That's why I stuck with that.
Q Okay. And have you ever used the TVT Abbrevo product?
A I don't think I used it in my practice. I probably used in meetings, cadaver labs.
Q So it's correct to say that you don't believe you ever implanted the TVT Abbrevo in an actual live patient; is that accurate?
A That is accurate.
Q And the TVT-S product, have you used that product before? TVT Secure, sorry, it's abbreviated TVT-S sometimes. I'm referring to the TVT Secure.
A I did a few cases with that.
Q And you ultimately decided not to continue using that product?
A My personal experience was not extremely pleasing. And then some data came out, and I decided not to consider it within my arm of interest.
Q And are you aware of what kind of mesh is utilized in the TVT Secure device?

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A Same type 1 mesh we use for TVT.
Q And do you know whether or not it's laser cut or mechanically cut in the TVT-S?
A I do not know.
Q With regard to the TVT Exact, do you know what type of mesh is utilized in that place?
A It's the same type 1 polypropylene macroporous monofilament mesh.
Q And do you know whether the mesh in the TVT Exact is laser cut or mechanically cut?
A I don't know.
Q And Abbreva; do you know what type of mesh is used in that device?
A Same thing.
Q And do you know whether that's mechanically cut mesh or laser cut mesh?
A I do not pay attention to that detail. It's irrelevant.
Q So the answer to my question is no, you don't know?
A No, I do not know.
Q Okay. Did you actually publish a poster or an article on the TVT Secure device at one point?
A TVT Secure, no.
Q So I want to go through your CV just a little

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bit, which I think is marked as Exhibit Number 5. This is your current curriculum vitae; correct?
A It's as current as when I last communicated with Paul's office.
Q Okay. And when did you prepare this CV?
A So, I mean, I try to update it as often as possible, but sometimes I'm too busy. So it must be from late 2016. The copy you have, there's a date at the top; right?
Q Is there? Yes, there is; October 18, 2016.
A Right.
Q So is this a document that you largely created in 2016, or is this more of a living document that you just kind of updated over the years?
A That's correct. I keep it in a Word format and keep adding to it.
Q Okay. And you've also published a number of articles. When's the last time that you'd say that you've specifically published on the TVT or TVT-O devices?
A So most of what I do involves pelvic floor surgery, so anything that I publish would have patients who had TVT or sometimes TVT-O as well. So specific to mid-urethral slings, it's been a while. If the objective is specific to sling procedures, it's been a while.
Q So fair to say it's probably been about ten years

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or so since you specifically published on the TVT or TVT-O device?
MR. ROSENBLATT: Object to form.
THE WITNESS: So everything I have includes patients who had slings placed. And some of the outcomes listed in some of those studies do include the involvement of those procedures, so I can't say it is that way you just expressed.
Q (By Mr. Faes) But in terms of a study that's specifically focusing on safety or efficacy outcomes specifically of a TVT or TVT-O device, it's been over ten years since you've published; correct?
A That's not correct, no.
Q When's the last thing that you published on them?
A So in 2014 -- so, for example, in 2015 there is -- actually, I did publish online last month a study, the Journal of Female Pelvic -- Female Medicine and Pelvic Reconstructive Surgery; very much about slings. The procedure which we did at that time, which was the objective of that study, was plication of mid-urethral slings when they fail at the first time. It just came out last month.
Q Okay.
A It's not included in that list, the one you

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have.
Q Got it. So when you were -- going back in time here, when were you first trained on a mid-urethral sling for the treatment of stress urinary incontinence; it was in 1999?
A 1999.
Q And at that time it was the TVT mechanically cut mesh that you would have been trained on; right?
A I did not question that, and I do not want to say it. Again, I do not pay attention to which it's mechanical cut or laser cut. Please do not ask me that again because it's irrelevant to me. 1999, whatever you know about TVTs at that time, you know that better because I never pay attention to it; it's a no event for me. So, yes, in 1999 I trained on whatever TVT offered.
Q And when were you first trained on a mid-urethral sling that's implanted through the obturator approach?
A 2003.
Q And what device were you first trained on for that?
A I did Monarc from AMS.
Q And when you was first trained -- or when did you first implant the TVT-O device made by Ethicon and Johnson & Johnson?
A It has to be a few years after Monarc.

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Q Okay. And so those -- so probably around 2005?
A I'm guessing.
Q So was there a period of time between 2003 and 2005 where you were regularly implanting the Monarc device for treatment for stress urinary incontinence?
A Correct.
Q And why did you -- was there ever a time where the TVT-O device made by Ethicon and Johnson & Johnson was the primary choice of treatment for stress urinary incontinence when a urethral approach was called for?
A At the time I was at Bay State Medical Center and our institution made sure that we had one product of any particular approach. And they ask general opinion and looked at the prices. At that time they thought AMS gave the best price. So that's why I used Monarc for transobturator approach most of the time in that hospital.
Q Understand. But my question was: Was there ever a time where the TVT-O device was your sling of choice, your primary option for a patient who needed a obturator sling?
A It could have been if it were available to me.
Q But, as you sit here today, is it correct to say you can't remember a time where that was the case, where the TVT-O was your primary option for treatment of stress

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urinary incontinence where an obturator sling was called for?
MR. ROSENBLATT: Object to form.
THE WITNESS: I liked my experience with TVT-O. It was pretty much no different from my experience with Monarc. But because hospital had one transobturator sling product available to us, that's why I used Monarc.
Q (By Mr. Faes) So if I understand your answer correctly, your answer is that you can't remember a time specifically where the TVT-O made by Ethicon and Johnson & Johnson was ever your sling of choice for treatment of a patient who needed an obturator sling?
MR. ROSENBLATT: Object to form.
THE WITNESS: Can you rephrase it?
Q (By Mr. Faes) I think you already answered the question, but you're giving the -- you're giving the explanation without giving the answer. So my question is: I understand the reason that you've stated why is because your hospital felt that the Monarc was a better option, but I just need to get the answer. Do you recall at any time in your career whether the TVT-O made by Ethicon and Johnson & Johnson was your primary option for treatment?
A It could have been.
Q But you can't remember?
A I would be indifferent if they were both

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available on the shelf to me. Would that answer your question?
Q Not completely. My question is: Can you ever -- sounds like you're saying you can't remember. Do you remember if there was ever a time where the TVT-O was your primary --
A I remember well that I like both devices. But in my hospital, TVT always not available; what can I do? I use Monarc. How do you like that?
Q Right. So it sounds like the TVT-O was never your primary option for your treatment of urinary incontinence?
A That is not true. You are misstating what I'm saying. That is wrong. What I'm saying is if they were both available at the same time on the shelf for me, I could have used either one.
Q So you would have no preference between --
A Correct.
Q -- the TVT-O --
A Lovely.
Q -- and the Monarc?
A That's good.
Q So I kind of lost track here so I want to circle back a bit. We were talking about, you know, consulting work that you've done for medical device and pharmaceutical

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manufacturers, and I think that we've established that you've been a consultant and an investigator for Coloplast; right?
A We already discussed that.
Q Right. And you received payments from Caldera Medical before; is that accurate?
A I might have. I'm not sure. If anything, must be very limited.
MR. ROSENBLATT: I don't want you to guess. If you have, you have. If you haven't, you haven't, but you don't need to make up any numbers.
THE WITNESS: I don't remember.
Q (By Mr. Faes) Okay. And -- but if I were to go on -- you know, there's websites now that disclose how much doctors have been paid by medical device companies; right?
A Right.
Q If I were to go online and see that you've been paid by Caldera in 2015, received a payment from them, you'd have no reason to dispute that, would you, as you sit here today?
A If it happened, probably for a dinner meeting, maybe. That's all I can say. I don't remember the details of working for Caldera as a consultant.
Q And you've worked for C.R. Bard as a consultant

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before; right?
A I had advised them on their device process, yes.
Q And C.R. Bard is also a manufacturer of synthetic mesh products for stress urinary incontinence and pelvic organ prolapse; right?
A That is correct.
Q And, in fact, specifically you consulted with them regarding some of their synthetic mesh devices for those indications; right?
A That's correct.
Q Do you remember attending a cadaver lab with them in 2009 for a product called WEB TO?
A I remember attending a cadaver program when they were developing some products, yes.
Q Do you remember what type of product that was?
A I don't remember the details about it.
Q If I represented to you that that particular product was a prototype product for the treatment of pelvic organ prolapse which was lighter weight than their current offering at that time, which was the Avaulta, would you have any reason to dispute that?
MR. ROSENBLATT: Object to form.
THE WITNESS: I wouldn't remember the details.

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Q (By Mr. Faes) And you've consulted for American Medical Systems or AMS before; right?
A Yes.
Q And they're a manufacturer of mesh products for stress urinary incontinence and pelvic organ prolapse?
A Correct.
Q And you've received payments from Intuitive Surgical before?
A Correct.
Q And you've received payments from Astellas Pharmaceuticals before?
A Correct.
Q You've received payments from Allergen before?
A That I don't remember.
MR. ROSENBLATT: Andy, all these questions you're saying received payments, you're not talking about litigation consulting, you're talking about just general consulting; is that how you're framing the questions?
MR. FAES: Well, the question is what it is, so if the Doctor doesn't understand it --
THE WITNESS: So I guess --
MR. FAES: He'll let me know.
THE WITNESS: Some of them you're now talking about might be dinners.
Q (By Mr. Faes) Okay.

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A A bunch of them are dinners. I have a strong feeling like Allergen or Astellas, very likely they were dinner sessions when maybe they paid our meal.
Q Okay. And what about Cogentix Medical, C-O-G-E-N-T-I-X?
MR. ROSENBLATT: Object to form.
THE WITNESS: I don't remember that particular company.
Q (By Mr. Faes) Okay. And just to be clear, you know, going back, I think we covered on -- with regard to Coloplast and C.R. Bard and Ethicon, it wasn't just for dinners, it was actually consulting for them on their products; right?
A So that is wrong. So Coloplast was 522 study, so true research. And Ethicon, it was advisory meetings. And then the third company you said, AMS?
Q C.R. Bard.
A C.R. Bard, also advisory on their product development.
Q And that would be consulting work; right?
A That's consulting, yes.
Q And what about AMS?
A AMS again, the work with AMS in two different ways; one was I had a innovative idea and they collaborated with me. We developed a product.

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MR. ROSENBLATT: And I'll just caution you to the extent anything is privileged or confidential between you and those companies, I ask you to keep that to yourself. If it's not privileged or confidential, you can discuss it.

THE WITNESS: So it was to test that product, I was their advisor and collaborator. Also, few times I preceptored for them and also advised them on their product development as well.

Q (By Mr. Faes) And you would consider that consulting work; correct?

A That's correct.

Q And what about Boston Scientific; I don't think we covered that one before?

MR. ROSENBLATT: Object to form.

THE WITNESS: It was, again, advisory and sometimes as a preceptor function.

Q (By Mr. Faes) So if you were a preceptor, that would also be considered consulting work; right?

A That would be within that realm; yes.

Q So it's fair to say that including Ethicon and Johnson & Johnson, you had either been a consultant or an investigator for at least five different companies that manufacture synthetic pelvic mesh; right?

MR. ROSENBLATT: Object to form.

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THE WITNESS: That sounds right.

Q (By Mr. Faes) Okay. And all of those relationships predate when you first became a litigation consultant for Ethicon and Johnson & Johnson; right?

A That is correct.

Q Now, you also -- I'm not going to get into this too much, but you've also been retained as Ethicon and Johnson & Johnson to do and write up some case specific expert reports; right?

A That's correct.

Q How many of those have you done so far?

A Five.

Q Has there ever been a case that Ethicon and Johnson & Johnson has sent to you to look at where you went back to them and told them I don't think I can support -- I don't think I can offer an opinion in this case, that you thought that the mesh device actually caused the patient's injury?

A There has not been any.

Q And have you -- well, strike that.

So so far 100 percent of the time when you looked at cases sent to you by Ethicon and Johnson & Johnson, your conclusion has been that that patient's complaints were due to something other than the mesh; right?

MR. ROSENBLATT: Object to form. If you

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want to get into each of those, then we can have a deposition on each of them within the respective time period, but he has not been reviewing those reports. He's here to discuss his TVT, TVT-O general report.

THE WITNESS: I rather stay focused on this topic, if you don't mind.

MR. FAES: Well, I mean, it's relevant, you know, as to his general deposition. So let me see if I can phrase it another way.

Q (By Mr. Faes) You agree with me that you've never represented a plaintiff, a person who's -- strike that.

You agree with me that you've never written an expert report or offered testimony supporting a plaintiff who was suing a mesh manufacturer for alleged injuries; right?

A I am not.

Q Okay. What percent of your practice would you say is spent treating stress urinary incontinence?

A So 90 percent of what I do is for urinary incontinence and prolapse, and many of those patients have both. So stress urinary incontinence is one of the types of incontinence types, and -- I mean, the question's not really very good. I'd say 50 percent of my patients, I think, have urinary stress incontinence.

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Q Is it fair to say that 100 percent of your practice is treating women or not?

A That is correct, I'm a gynecologist.

Q So currently how many surgeries would you say you do for the treatment of urinary stress incontinence -- surgeries for urinary stress incontinence do you do?

A Six a week.

Q For SUI?

A (Witness nods.)

Q And are those generally all slings?

A I can't imagine any other treatment for urinary stress incontinence.

Q So the answer's yes?

A Yes.

Q And how many pelvic organ prolapse surgeries do you have on average?

A So about maybe half of these patients have pelvic prolapse.

Q So about three or so a week?

A I think so.

Q How often would you say you do a surgery to treat mesh complications?

MR. ROSENBLATT: Object to form.

THE WITNESS: Rarely.

Q (By Mr. Faes) So if you had to put a number on

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it, about how many times a year would you say that you do a surgery to treat mesh complications?

MR. ROSENBLATT: Object to form.

THE WITNESS: It would be about five to ten a year.

Q (By Mr. Faes) And has that been pretty consistent over the course of your career?

A So I've been at Yale for two years and my role here is slightly different. I am running a larger division here with more research, other activities. So my clinical activities also have been affected by it, and job change also changes your patient population. Previous to that I definitely did, sometimes twice as many surgeries. And then probably all of these numbers would be like two-fold.

Q Okay. Let me see if I can ask it another way. Over the course of your career, how many surgeries do you think you've done to treat mesh complications?

MR. ROSENBLATT: Object to form.

THE WITNESS: I can't remember.

Q (By Mr. Faes) Well, if you've done five to ten on an average year, would it be fair to say that you've probably done more than 50 surgeries to treat mesh complications over the course of your career?

MR. ROSENBLATT: Object to form. And,

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Andy, are you asking about urinary stress incontinence mesh or any mesh? I just -- that's why I'm objecting.

MR. FAES: I mean, the question is what it is.

Q (By Mr. Faes) Over the course of your career, would it be fair to say that you have performed at least 50 surgeries to treat pelvic mesh complications?

MR. ROSENBLATT: Object to form. Vague.

THE WITNESS: So I'm not sure what that question aims to find out. First of all, question should be made clear, just like Paul is saying. Specific to urinary stress incontinence, you're asking?

Q (By Mr. Faes) Well, we'll break it down. If you need me to break it up --

A Let's do that.

Q So how many surgeries to treat complications from stress urinary incontinence products would you say you've done over the course of your career?

MR. ROSENBLATT: Object to form.

THE WITNESS: So what exactly are you talking about complications; when you say complications?

Q (By Mr. Faes) Well, you're a doctor; whatever you deem to be a complication from the surgery?

A So I don't understand that. Please tell me specifically what you want me to tell you. Are you talking

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about mesh extrusion, are you talking about voiding difficulties?

Q I'm talking about any situation where you had to go in and do an additional surgery due to some complication from the sling?

A What is the complication? Define complication for me.

MR. ROSENBLATT: Andy, that's different. Before you were asking about mesh complication; now you're just saying complication, so --

THE WITNESS: Yeah, exactly.

MR. ROSENBLATT: I think if you clarify.

THE WITNESS: Say it.

MR. ROSENBLATT: Ask him what you're trying to ask him.

Q (By Mr. Faes) So my question is: How many revisions of mid-urethral sling -- let's back up and start a little more simply. First of all, how many mesh removals have you done over the course of your career?

MR. ROSENBLATT: Object to form. Be more specific.

THE WITNESS: Specific to mid-urethral slings, are you asking?

Q (By Mr. Faes) No, any pelvic mesh removal that you've done over the course of your career.

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MR. ROSENBLATT: Object to form.

THE WITNESS: So are you talking about patients of my own or those referred to me by other people?

Q (By Mr. Faes) I'm talking about mesh removals that you've personally performed, whether you put the mesh in or somebody else put the mesh in?

MR. ROSENBLATT: You're asking about any procedures using mesh, or you're asking any stress urinary incontinence?

Q (By Mr. Faes) I'm asking any pelvic mesh that you've removed -- how many mesh removals that you've done over the course of your career, regardless of whether you put it in or somebody else put it in?

MR. ROSENBLATT: Object to form.

THE WITNESS: Removal would not be the right word as well. Actually, sometimes we don't remove it; we go back and tweak it, we change it, how it sits. So if you're asking me all the patients who came to me, whether they had the surgery through me or through somebody else and had problems with the mesh inserted for the purpose of treating urinary incontinence, pelvic organ prolapse, I -- in my both institutions I am the referral guy for things like that. And I can remember things, again, maybe ten the max a year I would do a procedure

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like that.
Q (By Mr. Faes) So over the course of your career, how many do you think you've done?
MR. ROSENBLATT: Object to form.
THE WITNESS: I don't want to guess. I'm not keeping tabs. And, also, you have to keep in mind that I have done thousands of procedures, so that number is not really easy to interpret, if I say a number.
MR. ROSENBLATT: Andy, if you want to ask him more specifically, I think he might be better able to answer your questions.
Q (By Mr. Faes) So you estimate about ten a year and you've been in practice since 2000; right?
A I've been in practice. I would include -- like, I've been inserting mesh for incontinence and prolapse since 1999, actually even earlier than that because I did some Mersilene mesh, which was not a product of a company, we would just cut a piece of it, really, in my fellowship. I did that, too.
So, yes, you can go back to 1997, but when I really got started -- got involved in the urogynecology world and then as a fellow, so, yeah, how many years is that? 1997 to 2018.
Q 19 years; right?
A It's 19 years.

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Q So it's fair to say even conservatively, if you're doing about ten a year and you -- ten mesh removals a year and you've practiced for about 19 years --
A About 20 years.
Q -- conservatively, you've done --
A I said in my report as 20 years of mesh insertion for one reason or another to treat incontinence or prolapse.
Q So conservatively it's fair to say that you've probably done 150 mesh removals during the course of your career; correct?
MR. ROSENBLATT: Object to form.
THE WITNESS: Say it again.
Q (By Mr. Faes) I said conservatively, it's probably fair to say that you've done at least 150 mesh removals during the course of your career; right?
A I do not want to answer that.
Q So you don't know?
A I don't know.
Q Okay. But you do say in your expert report that you've implanted over 2,000 mid-urethral slings for urinary stress incontinence?
A That makes sense.
Q And how did you come to that number?
A That is -- I, at that time, made a very

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deliberate attempt to get the right number approximately and went back to any record I could find to be as exact as possible.
Q So you felt it was important to do that; right?
A I guess since I'm an expert on TVT, TVT-O sling today, I assume that you would ask me those questions.
Q So you felt it was important to get an accurate number for how many slings you've put in, but you can't give me an accurate number for how many you've taken out; is that correct?
MR. ROSENBLATT: Object to form. You have not limited your questions to stress urinary incontinence. I'm sure if you ask your question about stress urinary incontinence --
MR. FAES: Paul, I'm going to ask you to stop the speaking objections. If the doctor doesn't understand the question, he can ask me the question, but this is getting ridiculous.
MR. ROSENBLATT: You're misstating --
MR. FAES: I mean, these are questions that every expert has been asked. They've asked them without rancor, and if you're going to keep this up, I'm going to file a motion to strike, I'm going to ask for more time and we're going to have to take it up in front of Judge Ifford (phonetic); okay?

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These are not controversial questions. If he doesn't know the answer to the question, he can say he doesn't know the answer to the question. But these speaking objections need to stop. If he needs clarification, he can ask; but this has to stop, Paul.
MR. ROSENBLATT: I'm trying to make it stop because I want to help you.
MR. FAES: No, you're not.
MR. ROSENBLATT: No, ask specifically stress urinary incontinence and I will stop objecting.
MR. FAES: I will decide the questions that get asked, Paul, not you. I don't have to frame them to your liking or the doctor's.
MR. ROSENBLATT: Your questions are drawing the objections, so if you want to phrase it --
MR. FAES: And these time limits are based on the expectation from Judge Ifford that the witness is going to be responsive to the question, and, as you know, Judge Ifford has ruled many, many times that if a yes or no question is asked, that you first answer the question yes or no --
MR. ROSENBLATT: You're burning your clock. Just go ahead and ask your questions. You're burning your own clock right now.
MR. FAES: Well, I'll burn my clock the way

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I want to. So I --
MR. ROSENBLATT: Okay.
MR. FAES: I just want you and the witness to be aware that the judge has ruled on this issue that if a yes or no question is asked, that you need to first answer the question yes or no, or if you can't answer it with a yes or no, then you state that, and then if you need to provide an explanation that's responsive to the question, after your answer you can do so.
MR. ROSENBLATT: Doctor, you can answer however you feel is appropriate --
MR. FAES: No, Paul that is not --
MR. ROSENBLATT: -- responsive. And to the extent you can answer with a yes or no, I encourage you to do so, but if you need to provide an explanation, then you're entitled to provide your explanation. Andy, if -- I'm done. You can continue to ask him.
Q (By Mr. Faes) All right. Well, let's start again, Doctor. Now, your expert report you've stated that you've implanted over 2,000 mid-urethral slings over the course of your career; correct?
A Correct.
Q And you feel confident in that number; correct?
A I'm quite confident.
Q And you felt that it was important to put that

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number in your expert report; right?
A Correct.
Q And you felt it was important to get an accurate number to put in your expert report; right?
A That's correct.
Q You'd agree with me that nowhere in your expert report is there any information regarding how many slings you have removed over the course of your career?
A I don't think it's spelled out.
Q Are you able to give me that number, as you sit here today?
A I cannot be accurate, but a rough calculation based on the numbers you just offered, I would say ten a year times, maybe -- we said twenty. What is that? 200, but there probably was less at some point, so let's say at least 100.
Q So you'd agree with me that you've removed mesh -- pelvic mesh from patients at least 100 times over the course of your career; right?
A It's not removal only. Sometimes it's repositioning, sometimes it is loosening.
Q So you'd agree with me --
A Sometimes it's releasing or cutting.
Q So you'd agree with me that you removed or revised surgically pelvic mesh in patients at least 100

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times during the course of your career; right?
A Yes.
Q And what percentage of that would you say was slings; are those 100 cases all slings or are we talking about all meshes there?
A As you already specified earlier, for all pelvic floor problems, if the mesh is inserted, those are the numbers we just talked about, so just to make it clear. And then when it comes to slings, maybe half of them were for slings. Most were not for removal, I can tell you that.
Q Okay. So it's fair to say that you probably removed or surgically revised mid-urethral slings at least 50 times during the course of your career?
A That is fair.
Q Okay. Doctor, you'd agree with that you're not an expert in chemical engineering; right?
MR. ROSENBLATT: Object to form.
THE WITNESS: I do not agree with you on that.
Q (By Mr. Faes) So you hold yourself out as an expert in the area of chemical engineers?
A I am an expert when it come to the devices I use, whether it's from the aspect of chemical engineering, or mechanical engineering, or anatomical design, or

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physiological design, but the logical aspects of it, I am an expert.
Q So do you have any training or background in chemical engineering?
A I went to medical school, I did chemistry, I kept up with all that. And when it come to devices I'm using, I read way more than anybody else has read on it so I am an expert.
Q Would you agree with me that you have no background or training specifically on polymer chemistry?
A I did not go to school for it; you're right.
Q Okay.
A Except I train myself, educated myself on it because it's something I use on a regular basis so I am an expert on the type of devices I use if they are made of polymer material.
Q So you believe you hold yourself out as an expert on polymer chemistry?
A Specifically to my topic, my area, yes, I am an expert when it comes to the use of those materials.
Q So what formal training or education have you had in that area?
A As I said, I studied chemistry in school. And then I kept up my chemistry knowledge. And whenever it came down to the knowledge of polymers for any specific

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device we used, I kept reading on it and discussing on it. I know more than anyone in this room about it.
Q Have you ever done any research specifically in the area of polymer chemistry?
A I have not studied polymer myself.
Q And you never published in the area of polymer chemistry; right?
A I have not published. When I say study, in the research form I mentioned specifically.
Q And you agree me that you've never done any bench research on polypropylene?
MR. ROSENBLATT: Objection to form.
THE WITNESS: I've been involved in bench research. Maybe I was not one of the authors.
Q (By Mr. Faes) What bench research were you involved in with polypropylene specifically?
A So throughout my career, when device companies were coming out with their products I've been approached with my opinion on different materials. And I've consulted, worked, halt, advised on their outcomes, their design choices. In our meetings we keep talking about these things. This is a hot topic, yes, I am an expert on that.
Q On lab research on polypropylene?
A I am an expert on any type of research when it

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comes to polypropylene or similar materials used for pelvic floor implantation.
Q Have you ever done any kind of pathological analysis on explanted polypropylene mesh?
A I study those all the time. It's my work; I am a pelvic floor doctor.
Q And what kind of analysis do you do on those examples?
A I study them like no one else does and that makes me an expert.
Q But you don't hold yourself out as a pathologist; right?
A Why would I; that's a licensure? I hope no one does without going through the entire residency.
Q So you wouldn't hold yourself out as an expert in the area of pathology; right?
MR. ROSENBLATT: Object to form.
THE WITNESS: That is specific to my area. I am an expert in pathology when it comes to the use of applications of pathology in my field.
Q (By Mr. Faes) So you wouldn't hold yourself out as a pathologist, but you consider yourself an expert in pathology; do I have that correct?
A Correct.
Q Would you agree with me that you are not a

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biomaterial specialist?
A I understand a lot more than most people on that, therefore, I am an expert in biomaterials being used in my area.
Q What qualified you to be an expert in biomaterials?
A 30 years of training, education and practice. Day in, day out, this is what we do. I'm not sure what you're talking about.
Q Would you agree with me that you've never published any opinions that polypropylene does not degrade in the human body?
A Ask me the question one more time.
Q Would you agree with me that you personally never published any opinions about whether or not polypropylene degrades in the human body?
A I did not.
Q Have you ever published any opinions concluding that polypropylene does not create a foreign body reaction?
A I have not published on those.
Q Do you consider yourself an expert on warnings for a medical device?
A Certainly.
Q Can you tell me what risk information medical

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companies are required to put in their IFUs or instructions for use?
A So, you know, as you know, there are federal and state rules, right, regulations. So if I want to come up with a new medical device, I go to FDA. Whatever FDA says I must fulfill. So FDA tells them to put in information on the IFU, they got to do that. So that's what I pay attention to. So if they obey FDA rules in whatever product they're marketing in any state and following those state rules as well, then they fulfilled their obligations.
Q And can you tell me what the rules say about the information that medical device companies are required to put in their IFUs?
A So it's written in the federal law that -- you know, FDA regulations are clear on it. And they just look at it, whatever they have. And there's a current practice, every year it's getting tighter and tighter. And the interpretation makes a difference, clearly, but because of the concerns they're getting even harder, just a few pages. So an FDA is extremely obsessive about the terminology, and I think that is -- they're doing a good job with that.
Q Are you familiar with what industry standards govern warnings on medical devices?
A Ask me again.

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Q Are you familiar with what industry standards govern warnings on medical devices?
A Ask me some other -- I don't understand that question.
Q Are you aware of any -- can you -- yeah, strike that.
Can you tell me any industry standards that govern what warnings should be in a medical device?
A Define industry standards for me.
Q Well, it's any industry standard. Are you familiar with any? Do you know about any Ethicon internal standard?
A Okay. Please spell out what you mean when you say industry standard.
Q I mean a standard that's followed within the industry.
A You're -- like conventions?
Q No.
A What is a standard from the industry standpoint? I know the standard in medicine, standard of care. Like, define what you are saying.
Q That's what I'm asking you. Are you aware of industry standards that govern what warnings should or shouldn't be on the instructions for use for a medical devices; can you name any?

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A So all I know is standards is set by the federal government and the states. As long as they're followed, medical device companies fulfill their jobs.
Q So it's correct to say that you're not aware of any industry standards beyond what is required by the federal government and the state; correct?
A You have not been able to tell me what exactly you're asking.
Q Right. I'm asking are you aware of any industry standards, other than standards imposed by the federal government or the state?
A I'm not sure what you mean by saying -- I've been asking you what you're saying, industry standards. What is industry standard you're talking about? Give me examples maybe if you cannot really explain exactly in words real -- clearly define it so that it's clear and transparent.
Q Are you aware of what Ethicon internal standards govern what warnings need to be in a IFU for a medical device?
A I know one thing about Ethicon, that actually they do a great job in following the law before they bring any product to the market.
Q So you're not aware -- I mean, you're stating that Ethicon does a good job of following the law. You're not aware of any instance where Ethicon marketed a product

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in the United States where that product had not been cleared by the Food and Drug Administration?
A I didn't say that. I didn't say that. They're very diligent and meticulous and they follow the law. That's what I'm saying.
Q Are you aware that there's been at least one incidence with a pelvic mesh product where Ethicon and Johnson & Johnson marketed that product for a period of several years without having clearance from the Food and Drug Administration; are you aware of that or not?
MR. ROSENBLATT: Object to form.
THE WITNESS: I don't know.
Q (By Mr. Faes) Do you know what departments of a medical device company are involved in creating warnings for a IFU or instructions for use?
A Regulatory.
Q Any others?
A R & D, marketing, sales.
Q And have you looked at what the departments at Ethicon and Johnson & Johnson, those departments had to say about the contents of the TVT and TVT-O IFU before reaching your opinions in this case?
A I looked at whatever was made available from the standpoint of the company documents, and, yes, I don't know if I have any problem.

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Q Well, for example, did you look at the testimony of Susan Lynn who was Ethicon and Johnson & Johnson's representative -- corporate representative on the issues of what needed to be in an IFU and what standards Ethicon and Johnson & Johnson followed?
A I don't remember specifically what that was.
Q So, as you sit here today, and I'll represent to you it's not on your reliance list, you don't remember ever reviewing the testimony of Susan Lynn; right?
A Is it on the reliance list?
Q Not that I see. I mean, you've only reviewed two depositions, right, Dr. Wiseberg and Dr. --
A I see; right. Then that's it.
Q You think it would be important to review the testimony of Ethicon corporate representative on the policies and procedures that Ethicon followed for determining what needed to be in the IFU before reaching your conclusions in this case?
A I believe I had all the information I need to come to a conclusion on whether Ethicon did the right thing about IFU or not.
Q Have you ever reviewed the FDA Blue Book Memo on labeling in forming your opinions in this case?
A I am familiar with that. I did not specifically review that for this case.

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Q Would you agree with me that a company should include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device, regardless of whether or not a causal relationship has been proven?

MR. ROSENBLATT: Object to form.

THE WITNESS: So I really disagree that you cannot spell out everything which happens associated with insertion of a device. First of all, when you do surgery, any kind of surgery, with or without implants, there's all kinds of risks, and some are not associated with the device itself. So specific to device, I understand, but those risks which come from inherently from the type of surgery being done, I don't see any reason why that should be included in an IFU because I, as a fourth year medical student, learned already that I must be very cautious when I'm doing surgery. It's not a child's play. I got to be very careful at every step of it. I must be like a hawk watching for the signs and symptoms of complications.

So it does not have to be in the IFU. I don't think any physician looks at the IFU when it come to understanding the risks of any procedure. We don't look at IFUs.

Q (By Mr. Faes) So you don't believe that that's the standard that should be followed; is that correct?

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A IFU is what FDA wants. Once you get FDA's approval in your IFU, you're good to go. The rest is up to me. Once you give that product to me, the outcome of that product depends on me. If I'm a lousy physician, I will do wrong things. If I am a good doctor, I will use it for the best purpose, and I will use it with the most caution, and I will inform my patient about it.

Q Well, do you know whether or not that's one of the standards that the FDA has set forth in their labeling guideline, that a manufacturer should include an appropriate warning if there's a reasonable evidence of an association of a serious hazard with the use of the device?

MR. ROSENBLATT: Object to form.

THE WITNESS: What I believe is Ethicon followed the regulation to the T for the time they were asked to do their IFU, and every time they updated it for the climate we have in this country in a reasonable way.

Q (By Mr. Faes) So going back to my question. My question, though, is: Do you believe that that's the appropriate standard to follow or not, that a manufacturer should include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device?

MR. ROSENBLATT: Object to form.

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THE WITNESS: No.

Q (By Mr. Faes) Okay. And do you know whether or not that's one of the rules that the FDA has set forward?

MR. ROSENBLATT: Object to form.

THE WITNESS: FDA wouldn't like it if it didn't do it that way. FDA allowed it to go through, so it's up to FDA then whether to like it or not.

Q (By Mr. Faes) So it's your opinion that if the FDA clears the device and the labeling included with that device, that that's -- they met the requirements and that's all they have to do?

A That's good enough for me, because I, as a surgeon, am responsible for the rest of it. As a pelvic surgeon, when we go to the OR we know we're not going to county fair, so every step of that surgery I must make sure I am following the teachings of my mentors and using the best technique, knowing the anatomy. I prepped the patient for it and I followed the patient for it. So I don't need a drug company or medical device company to tell me watch for these things, because it's in my books. I teach it.

Q Well, do you know whether or not a IFU or instructions for use can make it out into the market, and the FDA can later decide that that product is misbranded, meaning the product is correct; do you know what FDA misbranding is?

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A Right. So they could ask for changes and upon maybe the events coming out, reported to them, then they deal with that. And I think Ethicon dealt with that each time in a reasonable way.

Q Have you ever drafted an IFU or instructions for use on a medical device?

A Actually, I did for my own device, which is not on the market yet.

Q Is that the pessary device that's mentioned on your website?

A Right.

Q Are you working with a company working on that?

A No, I have my own company. I'm pursuing it myself with my son.

Q Okay. And do you know if that's going to be considered -- what is -- what class device that's going to be considered; is that a class I, II or III?

A Class II 510(k) process.

Q Okay. Is it fair to say that you never drafted a IFU or instruction for use for a class III medical device?

A I have not.

Q And it's accurate to say that you never drafted an IFU for a medical device that's actually been cleared or approved or gone on the market; right?

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A I don't remember.
Q Okay. Other than your one experience working on an IFU or instruction for use for the pessary device that you're developing, have you ever worked on warnings for a medical device?
A I don't remember.
Q Have you ever worked on warnings for a prescription drug?
A I don't remember.
Q Would you agree with me that a physician should be made aware of all the significant safety risks associated with a product in the IFU or instructions for use?
A No.
Q Would you agree with me that a manufacturer of a medical device that will be implanted in a women's body is required to disclose all significant risks to a doctor that comes with the use of that device?
MR. ROSENBLATT: Object to form.
THE WITNESS: Definitely no.
Q (By Mr. Faes) Would you agree or disagree that the warnings and adverse reactions section of an IFU or instructions for use should include all significant risks and complications related to the use of the TVT?
A I said no.

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Q Okay.
MR. FAES: Now might be a good time for a break.

(Off the record at 3:35 p.m.)
(On the record at 3:41 p.m.)

Q (By Mr. Faes) Doctor, we're back on the record after a short break; are you ready to proceed?
A Yes.
Q Now, on page 14 of your report you state and cite a section of the code of federal regulation. You say, "The IFU for the TVT and TVT-O are detailed and cover all the requirements set forth by the code of federal regulations 21 CFR 801.109(c);" You see that?
A Yes.
Q How did you come up with that specific of the code of federal regulations?
A It might be through my discussions and readings with the Ethicon material.
Q Okay. So prior to becoming an expert in litigation for Ethicon and Johnson & Johnson, have you ever read or reviewed this particular provision of the code of regulations?
A I had read it a few times.

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Q Okay. And when had you read it?
A Many years ago when I thought I was coming up with the device first, and then later for the pessary work, and then maybe this time.
Q Okay.
A So at least a few times before I read that code in detail.
Q So you don't hold your -- but you don't hold yourself out as an FDA or regulatory expert; right?
MR. ROSENBLATT: Object to form.
THE WITNESS: I am an expert in that area.
Q (By Mr. Faes) So you hold yourself out as a --
A Yeah.
Q -- regulatory expert?
A I am. I am definitely.
Q Do you hold any regulatory certifications or belong to any regulatory societies?
A I do not.
Q Have you had any formal education or training in that area?
A I don't think anyone needs it. Just read the code, be a doctor; you'll understand it better than anybody else.
Q Do you have any experience interpreting the code

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of federal regulations or other statutes, other than in this case?
A Specific to medicine, I am very good with that.
Q Have you ever served as an expert in that area, interpretation of statutes or regulations?
A I don't remember.
Q Are there any other statutes or regulations that you're relying on other than 21 CFR 801.109(c) cited in your report for your opinions that the TVT and TVT-O IFUs in this case are adequate?
A So over the years I educated myself on the FDA law as much as I could at any circumstance where my expertise was needed. Sometimes for the devices we thought we would come up with, sometimes maybe -- during the advisory process through the companies I was asked what to include and, therefore, I had to study these things.
So I had to rely on specific code and specific numbers of the code, and also related extra readings. So I've read 100s of pages of FDA material at many different steps of my life that I feel myself an expert in this area.
Q So maybe I asked a bad question. I'm just asking in this case are you relying on anything specifically, other than 21 CFR 801.109(c) as stated in your report for your opinions that the TVT and TVT-O warnings are

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adequate?
A Correct.
Q Is there anything else?
A Yes, the rest of the FDA code. This is just to make it crystal clear that this was cited that way.
Q Are you relying on any FDA guidance or regulations?
A I am relying on the written law and things which interpret it in many different ways. And the advices you would find through the FDA material for the companies, for the inventors, anyone who want to bring any product to the FDA's interest.
Q Are you relying on the FDA's Blue Book Guidance Memo for your opinions in this case?
A I would -- yes, I would consider that being part of the material I rely on.
Q And do you believe that that guidance -- strike that.
Do you believe that that Blue Book Guidance Menu should be followed by device manufacturers?
MR. ROSENBLATT: Object to form.
THE WITNESS: It all comes down to what is written in the law. And the rest is, as judged by the FDA, whatever the material is produced for the application. And then they look at it to see if they're

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meeting the criteria.
Q (By Mr. Faes) Would you agree with me that if a -- if the FDA issues guidance regarding --
A It's helpful.
Q Let me get the whole question out. You agree with me that if the FDA issues guidance regarding what warnings should be included in a medical device IFU, that a manufacturer should try and follow that guidance; correct?
MR. ROSENBLATT: Object to form.
THE WITNESS: That's not true.
Q (By Mr. Faes) So you don't think that a manufacturer should try to follow guidance documents put out by the FDA; is that accurate?
A I did not say that either.
Q You said both yes and no.
A Not really. You rephrased your statement and you made me think that it's the same; it really wasn't. So ask me one more question about it and then I will answer you one more time.
Q My question is: Do you think if the FDA puts out a guidance document regarding what warnings should be put in a medical device IFU, that a medical device company should try to follow that guidance?
A Whatever's written in the FDA law regulations

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must be followed. And the guidance documents are helpful, but everything should be looked at as a whole. And, finally, the decision comes from FDA. Whatever they have there, they will judge whether the company's meeting the regulation.
Q So is it your -- strike that. I'm just going to move on to something else.
Do you know what standard or standards a manufacturer must follow when designing mesh products?
A Ask me a specific question.
Q Do you know -- well, my question is: Do you know any standards that a medical device manufacturer must follow in designing; can you name any?
A FDA for medical devices made it clear. Just follow that.
Q So other than FDA regulations, are you aware of any standards that a mesh manufacturer must follow in designing mesh products?
A I would go by whatever FDA says.
Q Do you know what internal standards that Ethicon must follow in designing mesh products?
A I'm not aware of what internal standards are and would mean, but as long as FDA regulations are met, I am happy with the product.
Q Do you know what responsibilities a manufacturer

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holds in designing mesh products?
A Just like doctors, they got to be -- make sure that they're doing a good thing for the health care.
MR. ROSENBLATT: Object to form.
Q (By Mr. Faes) Do you know what types of experts are involved when a medical device company goes about designing a device?
A Yes, I do.
Q So what kind of experts are involved?
A As I said, the people who materials in experts, mechanical experts, engineers, these guys are typically engineers. Then you need the marketing people, you need the regulatory people, you need the salespeople; all of them have to be included in the product design, otherwise it's going to flop.
Q Do you know what a design history file is?
A Yes.
Q Did you review the -- well, first of all, what is your understanding of what a design history file is?
A Design history, like I had to do it for my own devices, that from day one we must document what we do with the development of the idea, even until it comes to the market. Every single step must be well-documented.
Q And did you review the design history file of the TVT or the TVT-O device before you issued your opinions in

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this case?
A I did study the paper where -- how they came up with the idea and all that. I don't remember if it was within my reliance design history thing. Is it there?
Q I'm asking you: Do you know if you reviewed --
A I don't think so. I don't remember doing that.
Q Do you know if you reviewed the initial design history risk assessment of the TVT device before it was put on the market in the United States?
A There were few scientific presentations and papers on it that I did read. And I saw how diligent and meticulous they were in finding the right type of material, the amount of material. They studied more than anything else I can imagine for the years they did this. I can't imagine better work than that can be done.
Q Do you know what Medscand is; are you familiar with that company or that work?
A Med scan?
Q Yes, M-E-D-S-C-A-N-D?
A I'm not familiar.
Q Okay. Do you know if you looked at the risk analysis of the TVT or not?
A I don't remember looking at that.
Q Do you know what the failure modes and effects analysis is?

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A Failure modes effect analysis, no.
Q Do you know what the purpose of a failure modes and effects analysis is?
A I am not familiar.
Q Do you know what a design failure modes and effects analysis is?
A No.
Q Do you know what an application failure modes and effects analysis is?
A I'm not sure if those refer to things I know, but just using a different terminology.
Q Do you recall if you ever reviewed any of the design failure -- strike that.
Do you recall if you ever reviewed any of the design failure modes and effects analysis for either the TVT or TVT-O devices in this case?
A No.
Q Do you know whether or not identifying the risks of the device is part of that risks of failure modes and effects analysis?
A No.
Q Do you know what kind of risks are to be assessed in the design failure modes and effects analysis?
A You already asked me whether I know, so, I mean, you're asking me the details about it. I already told you

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that the way you are calling it, I don't remember the specific work. But the type of work to analyze if a device is going to be effective or not, there are many different tests done to see. It could be physical testing, it could be mechanical testing, it could cytotoxicity testing, it could be bycopetalative (phonetic) testing. If you're covering those and using different terminology, then maybe I know some of those.
Q Have you ever reviewed any of Ethicon's internal standard operating procedures related to design?
A No.
Q Do you know how long it takes -- typically takes a product to get to market?
A I do, certainly.
Q And how long is that generally?
A Five years.
Q I noticed in your report that you've got the clearance date of the TVT-O product, or TVT product, rather, on page four you state that it was cleared by the FDA in January of 1998?
A Correct.
Q You see that? Are you aware of when the TVT-O product was cleared by the FDA?
A I don't remember off the top of my head right now.

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Q Do you recall what the development time was for the TVT-O product?
A A few years.
Q Okay. Doctor, you've got a little website, a little web page on Yale's University website; are you aware of that?
A Right, right.
Q And on that website there's about a one minute video of you talking about urinary stress incontinence surgery?
A I am on that; okay.
Q Do you know that or not?
A I haven't looked at it for a while. I remember they taped me when I first started.
Q Okay. I'll represent to you it's about a one minute video, you're wearing kind of a brown sport coat, all in brown. Do you remember shooting that video or when that occurred?
A It's been a while.
Q Okay. But was it within the last two years?
A Yeah, at least a year ago.
Q So that's about a one minute video, and one of the things you state in that video is that surgery for stress incontinence is so gratifying; do you remember saying that in the video?

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A Yes.
Q And it also states in the video that about 90 percent of patients are cured?
A I'm helping easily 90 percent of patients with stress incontinence surgeries.
Q Do you remember in that video whether or not there's any -- or have you reviewed the video to know whether or not there's any discussion of any risks to the patients in that one minute video?
A I'm not sure what that video is about, to be honest with you.
Q Okay. One of the things you state in the video, I'll represent to you, is you state every time a patient comes back, gives me a hug with the great results because they can get back to their routine; do you remember saying that?
A Yes, that's like my routine discussion with the patients. I really believe in sling procedure, it's a life changing procedure.
Q But is that really what happens every time? You've never had a patient who's been dissatisfied with the procedure?
A That's not a good question. Obviously, surgery is a risky business, things happen, and we inform the patient before going to the OR. But I can tell you if I go

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back, remember my memories, bring the memories back all these 20 years taking care of urinary stress incontinence, I know one thing I do well, did well for my patients is I treated their stress incontinence really well thanks to TVT and similar mid-urethral sling procedures.
Q But you've agree with me that not every patient that has a TVT sling, whether it be from you or another doctor, have a great result; right?
A Obviously not.
Q Okay. So this website video, do you think it's responsible to put that out there, a minute long video without informing patients of any of the risks?
A It is extremely responsible. Do you know why it is very responsible?
MR. ROSENBLATT: Object to form.
THE WITNESS: Because all patients are hearing are, unfortunately, the wrong things about mesh procedures, which is dinnertime, prime time TV commercials from law offices. And somehow we need to tell them how actually good these products are.
Q (By Mr. Faes) And that's what your video does, right, it explains the benefits, but none of the risks; right?
A The benefits, because, again, they're so well-informed, trust me, about the things, advertisements

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coming from it. Someone has to tell these people that these procedures serve 90 percent of women in the right way. That's what I'm saying.

(Plaintiff's Exhibit 7, 2009 Email, marked for identification.)

Q (By Mr. Faes) Doctor, I'm going to hand you what I'm going to mark as Exhibit Number 7 to your deposition. And this is an email that you're on dated 2009 and I'll give you a minute to read that.
A All right.
Q You done there?
A Yes.
Q So this is an email between you and Mr. Steel from Ethicon and Johnson & Johnson, who I assume is a sales rep or marketing person?
A Correct, like a more managerial.
Q And in this particular email he's offering to sponsor a dinner at your institution if you're willing to do a talk on the Prosima device; right?
A I'm not sure Prosima. Probably all the Ethicon products, I'm guessing.
Q Okay. Was that routine -- I'm going back to 2009 -- that Ethicon would agree to sponsor a dinner at

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your hotel if you were willing to give a talk on their products?
A So you misstated it. Say it again, please. Please read it carefully, see what the email says and then ask me the question one more time.
Q So my question is: Independent of the email, was it routine -- strike that.
Was it unusual in 2009 for Ethicon and Johnson & Johnson to agree to sponsor a dinner or event at your institution if you were willing to give a talk on their products?
MR. ROSENBLATT: Object to form.
THE WITNESS: It was really not routine. I'm not sure if it ever happened. I'm not sure a meeting like that ever happened, but it probably has happened a few times that the industry helped us organize maybe a meeting, typically not a dinner, like an education session with the potential patients to inform them about what we could do for their urinary incontinence and prolapse.
I don't remember specifics of this 9/29 basic urogyn meeting on hospital grounds; I really don't remember that. But I might have had few meetings where the industry provided food maybe for the patients so that we could tell them about their options for incontinence and prolapse.
Q (By Mr. Faes) Right. And that was something

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that Ethicon and Johnson & Johnson was willing to sponsor for you; right?
A All the companies like to do that with the physicians. I probably did it less than anybody else ever. That's pretty much routine in the industry, that companies like to sponsor those educational sessions. I don't think it ever happened with us and Ethicon then.

(Plaintiff's Exhibit 8, Invoice, marked for identification.)

Q (By Mr. Faes) Okay. Let me hand you what's been marked as Exhibit Number 8 to your deposition. And this is an invoice for a 2011 trip you took to an Ethicon summit in Sonoma, California; do you recall that?
A I do recall that, yes.
Q And this is an event that you appeared at as a consultant for Ethicon and Johnson & Johnson, they paid you for that; right?
A Correct.
Q And they paid you an honorarium, it looks like $500; is that correct?
A Correct.
Q And did they pay for your travel and expenses to Sonoma, as well?

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A Correct.
Q How many times would you say that you've taken trips or speaking events for Ethicon and Johnson & Johnson?
A Probably was it.
Q So you believe that that was the only time?
A I don't remember any other, but you bring it if there is any.
Q Do you recall ever traveling outside of the United States for Ethicon and Johnson & Johnson?
A I never did it under their payment. I did not take those trips to Europe. I did it myself.
Q Oh, so you did -- did you take a trip at some point to attend or speak on Ethicon and Johnson & Johnson products?
A No, no.
Q So I'm not -- to what are you referring?
A So I remember when some of these products were being designed they were taking some American physicians to really, I think, probably make their products better, get their opinions on it, and maybe get their experience on the cadaver labs, because most of these devices were invented in Europe. I've not been on any of those trips.
Q Got it. You never got the invite to go over to Sweden and train with --

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A That's not right, you said wrong. I declined invites.
Q So you were invited to go to Belgium and train with Dr. Delaval at one point?
A Right. I was invited a few times. Not through Ethicon only; other companies as well, but I just did not want to be involved in that at that time.

(Plaintiff's Exhibit 9, 2009 Email, marked for identification.)

Q (By Mr. Faes) Okay. I'm going to hand you what's been marked as Exhibit Number 9. And this is an email from you in 2009 and I'll just give you a minute to review that.
A Right.
Q So this is an email from you in 2009, and it's regarding getting the TVT back in the hospital that you were practicing at at that time?
A Right.
Q And what hospital was that?
A Bay State Medical Center.
Q So why was the TVT removed from Bayside Medical Center?
A Bay State Medical Center.

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Q Bay State.
A So I was a division director, I was basically kind of representing a group of physicians who were using sling products. So I remember that TVT, again, was more expensive. So because of that, and Bay State Medical Center did a good job looking for pricing and negotiating pricing. And they're asking our opinions as well. Obviously they would not necessarily bring a device which is not acceptable, but economic.
Anyway, so there was arguments going back and forth whether TVT should be there or not. So at some point TVT wasn't there, so we wanted to bring it back because it's almost the standard mid-urethral sling procedure. So we argued for that, that it should be there, offered. So that must related to that.
Q Do you recall for how long of a period of time that the TVT was not available at that particular hospital?
A I don't remember.
Q So during the time -- well, what period of time were you at Bay State Medical Center?
A I moved to Bay State 2004 and came here 2017.
Q Okay. So you can't recall, as you sit here today, the length of time that the TVT device was unavailable in Bay State prior to being reintroduced in

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2009?
A No, definitely not.
Q Do you recall what you were using -- and I'm assuming this is referring to the TVT -- TVT retropubic; right?
A TVT bottom-up retropubic, yes.
Q And during the time that the TVT was unavailable prior to it being reintroduced in 2009, what device were you using for the retropubic approach in your patients?
A Lynx, Advantage, SPARC, AMS products, I'm assuming.
Q So at that time those products were available in your hospital, the TVT was not?
A For a while TVT was not there because of price negotiations.
Q Okay.

(Plaintiff's Exhibit 10, 2013 Email String, marked for identification.)

Q (By Mr. Faes) Doctor, I'm going to hand you what's been marked as Exhibit Number 10 to your deposition. And this is a 2013 email string between you and some folks at Ethicon. You had a chance to review that document, Doctor?

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A Yeah.
Q So this is a document from Ethicon to you back and forth. And one of the things they're discussing is trying to get you to use some ARTISYN Y mesh for some of your cases; is that correct?
A So, yeah. I, mean, like any company, the salespeople are trying to get their products in. So, yes, they were developing the Y mesh, their ARTISYN Y mesh. And then also Ethicon acquired one of the new suture materials which we use in pelvic organ surgery, too. So it sounds as though they want us to use those things.
And so we were also organizing a meeting, educational meeting for the region. And most meetings commonly are sponsored by companies. So -- and they're disclosed, and I don't think any society can happen without sponsorship of the companies. So for this regional meeting we relied on the companies, which provided us products, so that was probably the discussion about it.
And what this indicates, that we would like them to have a booth so that they can show their products to the attendees, and that would be benefit to their own companies, and that would help us to do that meeting there.
Q Right. So they emailed you and asked you about the possibility of trialing this new ARTISYN Y mesh for

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pelvic organ prolapse in your practice, and your response was to ask them about potentially sponsoring a booth at your regional conference; right?
A So we don't get together with these guys very often, it's just very busy people. As soon as I see a company asking to come in to show their product, my brain works in a different way; I want to make sure that our meeting is sponsored. And as a director of the division, it was my job to make sure that we had a meeting and where the companies also have a chance to show their product. So that's basically about that.
Q Right. That was your response, right, you asked them about potentially sponsoring a booth in one of your conferences; right?
A And we never used that product. I never used that product.
Q Did they end up sponsoring a booth at your conference?
A They did, they always do. They have a budget for things like this. That's the way the whole medical device or direct company world function. And then for us, we do use their products. I guess somehow they feel obligated to support our hospital and an educational session like that, too. And we never trialed it.
Q Right. So you sent them a request to sponsor a

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booth and their request was to send you back an investigator initiated study or IIS request; right?
A So they thought this was -- this was I wanted them to sponsor one of those things. And I said it's not that, it's just basically you just be there, get a booth so that you introduce your product to the people.
Q Right. And then IIS request is just an investor -- initiated study; right?
A Correct, it's not -- doesn't meet that criteria, it's not that, that's not what we're asking.
Q Right. And that's what your response back to them was, is that it's not really an IIS request; right?
A It is not.
Q And you stated, "I will do whatever is necessary to do it right, thanks for the support;" what did you mean by that?
A So the paperwork was I will do whatever's necessary to make sure that you can get support. Whatever paperwork's needed, let's just get you in so that you can show your products and this meeting also gets your financial support so that we can educate people. All for education. Nothing but education. We did not even trial it. And they supported it. It's just the system how -- without the support from the companies, no educational meeting or conference can be completed.

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Q Right. So your response was because of your long-standing relationship with Ethicon, that you were going to do whatever you could to help them sponsor a booth at that convention; right?
A The intentions were whatever paperwork needs to be done, I'm ready to do it. So don't interpret it in any different way, please.
Q So in terms of IIS or investigator initiated study request -- so in terms of investigator initiated study request, you've actually offered to write those up and submit them to Ethicon before; right?
A I try for something else, maybe. I'm not sure.
Q Was it for the SECURESTRAP, perhaps, that you offered to --
A Correct.
Q And I think they ultimately told you with regard to the SECURESTRAP, that they were more targeting hernia surgeons at that time; right?
A Very good, exactly. I wanted to -- I thought it would fit with some of the surgeries that I did. And they were pulling out slowly from the pelvic floor market, and then they said, sorry, we're not focused on that area any more.
Q Okay. And as part of your relationship with Ethicon, you've actually allowed engineers from Ethicon to

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come and observe you while doing a surgery for one of their products; right?
MR. ROSENBLATT: Object to form.
THE WITNESS: It was using SECURESTRAP basically for a surgery, yes.
Q (By Mr. Faes) And that's what I was going to ask; you've anticipated my next question. I'm going to hand you what's been marked as Exhibit Number 11 there.

(Plaintiff's Exhibit 11, Email, marked for identification.)

THE WITNESS: Yes.
Q (By Mr. Faes) And that's essentially -- what Exhibit Number 11 is reflecting is that you allowed, upon Ethicon's request, a couple of engineers to come and observe you doing a SECURESTRAP in a patient with the patient's consent, of course?
A Yes, correct.
Q And that SECURESTRAP, you used that for a pelvic organ prolapse operation?
A I attached the mesh to the sacrum that way.
Q Okay. So let me ask you just a few things. Going through your expert report, here on page six of your report you state that "The annual economic burden of

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urinary incontinence is approximately $20 billion dollars, and the cost of nursing home admission, adult diapers, medical and surgical treatments and time loss from work are all taken into consideration;" do you see that?
A Correct.
Q And it looks like you got a reference there to an article?
A Yes.
Q Is that where you're taking that reference from?
A It's not the whole statement. Part of it must be coming from that if I put it in parenthesis right next to that statement.
Q Have you ever done an analysis of the economic burden of mesh complications from mid-urethral slings like the TVT and TVT-O from medical and surgical treatments, lost time from work and any nursing home admissions that are required?
A I have not done a study like that.
Q Okay. So, as you sit here today, you don't have any kind of estimate as to what the economic burden from mesh complications for mid-urethral slings is; right?
A I do not.
Q Okay. Further down on the page on page six you state that, "To date, the synthetic mid-urethral sling like

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the TVT and TVT-O are the best treatment option available for the index patient with SUI;" do you see that?
A Correct.
Q So it's your opinion -- is it your opinion in this case that any synthetic mid-urethral sling is the best treatment option, or do you have an opinion as to which is the best treatment option specifically for the index patient for SUI?
A So I would say in general mid-urethral slings, if they're made of type 1 mesh, they're all very good. But if I have to say that one product differentiates itself from the others, that would be TVT, specifically TVT. And TVT-O is almost next to it, because they've been on the market the longest, they've been tested more than all of them combined.
And the quality of the studies, number of studies, level of evidence supporting TVT, TVT-O surpasses all of them combined. So because of that, if I had to pick one, I would say TVT and TVT-O. But on the other hand, all the slings with type 1 mesh, full length mesh, I believe are helping women and not causing problems as much as you -- as much as litigation suggests.
Q So if I understand you correctly, you think that the best option for the index patient with SUI is specifically the Ethicon TVT and, secondly, the TVT-O?

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A So I would say, in general, I would be fine with the mid-urethral sling, which are still on the market. But if you ask me the one which has the best evidence, I would say those two.
Q But, currently, as we discussed earlier, you're not using the TVT-O for patients with an obturator?
A Correct.
Q Who need an obturator sling, you're using the Obtryx II; right?
A That's correct.
Q Do you tell your patients when you recommend a obturator sling to them that you don't think that the Obtryx II is the best option, that it's what you're limited to use because that's what the hospital has?
A In my hands there's hardly any difference in between. An Obtryx has been tested and tried in prospective manner in many studies. And my personal experience also supports that's a good product. So I have no problem presenting that to my patient. I -- the difference would be more technical in that situation.
Q So you think the Obtryx is a good product for obturator, but it's just not the best product?
A I would say it's a very good product. I can't say it's not the best product. I can say that TVT-O has been studied more extensively. From that standpoint, TVT

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might be a better supported product with evidence.
Q You also stated earlier that they've -- the TVT and the TVT-O have been on the market the longest; is that true with the TVT-O?
A No, TVT-O has not been the longest on the market. Yes, Uptake proceeded it and Monarc was before also TVT-O, but they got good track record.
Q You -- I believe you state in your report that at least at one time the Burch treatments was considered the gold standard for the treatment of urinary stress incontinence; is that correct?
A That's correct.
Q Would you agree with me that the Burch procedure for urinary stress incontinence is still within the standard of care today for treatment of urinary stress incontinence?
A No.
Q You don't think it's not within the standard of care?
A It's not any more.
Q So you think that any doctor that performs a Burch procedure is violating the standard of care?
A I wouldn't say so. Standard of care, I think, has been replaced by just overwhelming evidence in favor of TVT and the other mid-urethral slings. So fellowship

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programs are not teaching Burch any more. Fellows come out doing no Burch procedures. So these are the future urogynecologists who will treat your wife, my wife, my children; they don't have to do Burch.
Q So you're not -- sorry, I don't mean to interrupt.
A But they know both transobturator and TVT approaches so well, and I am confident they're going to do a good job when one of our relatives need help.
Q So it's your belief, as you sit here today, that there are not any fellowship programs in the United States that still teach the Burch procedure?
A That's wrong. Why are you stating that way? Ask me the right question.
Q So you disagree with that?
A I disagree with what you say.
Q So you agree that there are still fellowship programs within the United States that teach the Burch procedure; correct?
A Correct. We want to teach it, but, look, patients will not like it. When you have TVT and Burch and present the risks, complications, recovery and all that, no one is going to take Burch.
Q Would you agree with me that if after being presented with the risks and benefits of both, the

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mid-urethral sling and a Burch procedure, that the patient opts to go with the Burch procedure, that would be a reasonable option for that patient?
A In my opinion, it would be a lesser option for the patient, so I do not even present it. When they mention that they're worried about mesh insertion, I start telling them about everything else about Burch and they immediately -- and what I'm telling them is evidence. I don't tell my personal experience on these, only strong evidence. And they immediately are convinced that I'm giving you the best option, which has replaced Burch as the standard of care today.
Q But if you had, hypothetically, a patient that was presented with the risks of both procedures and they still decided I'd rather go with a Burch procedure because I don't want this synthetic mesh, would you agree that would be a reasonable option for that patient?
A I would try my best to convince her that she's making the wrong choice because I strongly believe that mid-urethral sling will do it in a less complicated way and faster recovery and everything else.
Q But you would ultimately respect that patient's wishes if they've decided?
A Correct.
Q Would you agree with me that the autologous

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facial sling is still within the standard of care for urinary stress incontinence?

A So, again, standard of care is mid-urethral slings. Those two are not in the standard of care any more. Those are options when patients refuse to have a sling. So standard of care, the go-to procedure if someone has urinary stress incontinence with or without urge incontinence, 99 percent of physicians in the world will offer the patient mid-urethral slings. There will be 1 percent, those are outliers.

Q And so what -- strike that.

Would you agree with me that similar to the Burch sling, if after hearing the risks and benefits of both, the mid-urethral sling with mesh, and the risks and benefits of the autologous facial sling, the patient decided to go with the autologous facial sling, that would be a reasonable treatment option for that patient.

A I would, again, do my best to convince her that she's not making the right decision. But, again, if she's so convinced that she's definitely not going to accept any mesh placement in the form of a strip, which is sling mesh, then I have no other choice, that I will have to follow the patient's request.

Q If you had a patient who ultimately decided that they wanted a Burch procedure, would you do that procedure

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yourself or would you refer that patient to another physician?

A I would definitely -- I am very capable of doing Burch procedures today, but how many of those do I do now? Like one, two, nine ratio -- no, one to nine -- I don't know when I did that Burch this past year. Not even that.

Q I'm not sure I got an answer to my question. My question was simply --

A I can do it. I will do it.

Q So you would do the procedure yourself as opposed to referring it to another physician?

A I will do it, because I have the skills to do it.

Q Okay. And do you recall -- you kind of anticipated my next question. The answer may be you don't remember, but can you recall the last time you performed a Burch procedure?

A Maybe two years ago.

Q Okay. Same question with autologous facial slings. If after hearing the risks and benefits --

A About a year ago.

Q That's exactly not the question I was going to ask so let me ask that question. When was the last time that you recall performing an autologous fascial sling?

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A About a year ago.

Q And the question I was going to ask was: If you had -- which I think I already know the answer to, but if you had a patient that after hearing the risks and benefits of both, the synthetic sling and autologous facial sling, decided they wanted to go with the autologous facial sling and you weren't able to talk them out of it, would you do the procedure yourself or would you refer them to another physician?

A I would do it myself. And I would do both procedures really well and to the best possible way for sure, because I have the skills.

Q Right. Of course you wouldn't do a procedure if you didn't feel like you could do it competently; right?

A Correct, so I maintain the skills to do both.

Q So on page eight of your report you talk about the laparoscopic Burch procedure. And you agree with me that the laparoscopic Burch procedure is minimally invasive; right?

A It is minimally invasive as is any laparoscopic surgery.

Q And you also state that "It requires skills which may take a longer time to require;" do you see that?

A That's correct.

Q Do you think that should be a consideration of a

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patient when deciding the best option for surgery, about whether or not it takes a longer time to acquire the skills for that particular surgery?

A Certainly, because most people probably will be in their learning curves to do laparoscopic Burch procedures; that translates to higher risks.

Q But you're not still in the learning curve for laparoscopic Burch procedures, are you?

A I am not in the learning curve; but, again, considering my skills to do mid-urethral slings and my outcomes from it, I cannot convince myself to do a laparoscopic Burch procedure today, because, again, the dissection requires way more skills. And TVT today is second nature to us.

Q So on page 11 of your report you state that "The utility, desirability and benefits of TVT and TVT-O significantly outweigh the risks;" you see that page 11?

A Yes.

Q Okay. And that's an opinion that you intend to offer in this case; right?

A Correct.

Q So in doing -- in coming to this, an opinion, I assume that you believe that -- you intend to offer an opinion in this case that the TVT is safe; right?

A TVT is very safe.

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Q And you intend to offer an opinion in this case that the TVT is effective; right?
A TVT is very effective.
Q And what do you think that the overall efficacy or effective rate is for the TVT?
A It depends on the measure you take. So I want to say 90 percent improvement, slash, satisfaction which translates, to me, subjective cure.
Q And so that's essentially what you've said on your one minute video on your website, right, 90 percent, I think you say cure, but --
A Subjective cure. Technically speaking, subjective cure is 90 percent.
Q So how low would the effectiveness rate of the TVT have to be before you decide -- strike that.
How low would the effectiveness rate of a medical device need to be for stress urinary incontinence before you would decide that it's not an effective treatment for stress urinary incontinence?
MR. ROSENBLATT: Object to form.
THE WITNESS: So I'm not sure I have a magic number. I think when we talk about a procedure we take everything into consideration. So effectiveness, safety, ease of use, desirability, utility, cost; all these are factors. So then I start thinking about that

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procedure. If it is graded high on all of these things in a composite way, maybe that's a good thing.
So zero risk, there's no such a thing, but 70 percent effectiveness is not a bad thing. Something which will not hurt anything, but is 70 percent effective, I would like that.
Q (By Mr. Faes) So if I understand you correctly, I think you're saying that, you know, the effectiveness rate for a device depends on large part -- the acceptable effectiveness rate depends on also the complication rate?
A You have to look at the device from all perspectives; correct.
Q So let me ask you this question: How -- first of all, what do you think that the overall complication rate is for the TVT, specifically the retropubic?
A Very low, extremely low.
Q I think in one point in your report you state that the complication rate of the TVT is around two percent. I assume you meant that the erosion rate is around two percent, not the overall complication rate; right?
A Correct, because everything else is related to doing any cutting on the patient. Like, if you cut someone there's a complication from it regardless of what you do. Make an incision, there's a complication; bleeding,

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infection, organ injury. And where do they come from? From just you cutting. So it's not TVT fault; it's procedure's fault. Any procedure has it. Guess what? Burch procedure has way more. Same for autologous; you're removing a piece of mesh from the -- tissue from a patient. Can you imagine, you're cutting a piece, taking it, putting somewhere else, additional risk from it.
Q So how high would the erosion rate, for example, need to be on the TVT or -- strike that.
How high would the erosion rate on a mesh device for stress urinary incontinence need to be before you would think that that device was not safe enough to use?
MR. ROSENBLATT: Object to form.
THE WITNESS: Don't ask me hypothetical questions, please.
Q (By Mr. Faes) I'm allowed to ask hypothetical questions. Is your answer essentially that there's no magic number?
A I don't have a magic number for you.
Q Okay. But you know that there are some synthetic slings on the market that were shown to have an erosion rate up to 30 percent and were removed; right?
A I'm sorry. Tell me -- be specific, please.
MR. ROSENBLATT: Object to form.
Q (By Mr. Faes) Are you familiar with the ProtoGen

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device at all?
A Yes.
Q And you know that that device has been removed from the market; right?
A Correct.
Q And would you agree that that was removed due to -- primarily due to safety concerns from high erosion rates; correct?
A Correct.
Q Are you familiar with what the erosion rates were for that device?
A It was very high.
Q But do you know the percent, as you sit here?
A I don't remember off the top of my head, but it was unacceptably high.
Q What if -- if the erosion rate was shown to be 30 percent, would you think that that's a high enough risk to determine that that device was not safe?
MR. ROSENBLATT: Object to form.
THE WITNESS: It depends on the volume of the studies, the level of the studies. There will be one outlier study on one particular instrument or device which will show you 30 percent. It's because they don't know how to operate in that hospital, I guess. It has happened in many studies for any kind of sling or mesh

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applications. Some places it was zero percent extrusion rate, some places 100 percent. How do you explain that? Am I going to go by that 100 percent or this zero percent?

So you look at the entirety of the literature and you look at the level of the literature. So you go by the grading score of the literature. So that 30 percent alone doesn't tell me anything.

Q (By Mr. Faes) Right. So if assuming that you look at the entire literature and it consistently shows an erosion rate for a SUI device for 30 percent or more, would you think that that device is not safe?

A It's systematic analyses, meta analyses on top of level one studies demonstrate that there's 30 percent risk of mesh erosion, extrusion, then that device should be looked at definitely.

Q So you agree with me that a 30 percent consistent erosion rate is certainly cause for concern and might force you to look more into the question of whether or not that device is --

A If the 30 percent comes from multiple studies all substantiating the same thing, then I would look at it as a serious consideration.

Q So how high would the erosion rate need to be for a SUI device before you start looking into it as a serious concern?

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A I don't have a magic number. I want to look at it again from the efficacy, safety and everything else, ease of use, utility, desirability, cost; all of that would have to play a role in any decision-making.

Q But we can agree that it's got to be somewhere between 2 and 30 percent, because the TVT, you think, has a 2 percent erosion rate and 30 percent makes you uncomfortable, so somewhere in that range; right?

A Correct, that makes sense.

Q But as you sit here today, you can't put a number on it; right?

A I don't want to set a bar there.

Q If you can't put a number on it, what objective standard are you using to determine whether or not a medical device like the TVT or TVT-O is safe?

A So subjective, objective outcome measures in terms of effectiveness, the adverse events cumulatively and how seriously the adverse events, all of that play a role. So cumulatively they would all be looked together and that will help us decide whether any procedure is safe to continue or just abandon.

Q But, as you sit here today, you can't put a qualitative number, other than somewhere between 2 and 30 percent; correct?

A I don't like to guess.

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Q Okay. Are you aware that at least in some studies the erosion rate for the TVT has been shown to be up to 19 percent?

MR. ROSENBLATT: Object to form. If you want to show him a specific study, you can pull it out.

THE WITNESS: Show me the study.

Q (By Mr. Faes) I'm just asking are you aware. Are you aware of any studies?

A There might be a study somewhere in esoteric journal.

Q So you believe that if there was a study of TVT showing a 19 percent erosion rate, that it was in an esoteric journal?

A What I'm saying is: I looked at the level of evidence, follow up, duration, prospective design. I look at the researchers who put it out, then I decide whether it's valuable for my interpretation or not. I disregard studies many times immediately as soon as I look at their methods. That possibly is one of those studies. But if you look at the literature from the quality standpoint, I don't think there's any study, there's any procedure which has been studied and substantiated as much as, like, in a favorable way, as much as TVT has been.

Q Yeah. We're --

A Any discipline of medicine --

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Q We'll get to that topic in a little bit, but I want to follow up on that. Are you aware that at one point Ethicon reported on its website the results of a study with TVT where the erosion rate was 19 percent?

MR. ROSENBLATT: Object to form.

THE WITNESS: I don't remember anything as such.

Q (By Mr. Faes) Assuming that they did that, do you think that Ethicon would put the results from a esoteric journal, as you put it, on their website?

A I don't know. It's up to Ethicon.

Q When you would counsel your patients, I would assume that you -- before a TVT procedure, I assume that you would inform them of the risk of erosion; right?

A Right.

Q And if they ask what the rate of erosion is, what would you tell them?

A I say two percent.

Q Okay. So you never at any point told any of your patients that you think it's 2 percent, but at least in some studies, according the Ethicon's website, it's been as high as 19, you've never told a patient that; right?

A A scientist would not go by one study, you look at the abundance of the literature. And they all indicate one number; two percent, one to three percent. Go look at

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it across the board, all the major reliable studies show that. So I'm not going to tell what one study did. I'm looking at level one high quality studies with the longest term outcomes, and systematic analyses and meta analyses. When I look at that, the number is one, one to three percent, and I say two percent; right in the middle.

Q So I think you are doing what you were doing before, which is giving me the explanation to the answer, which is fine, but I don't think I ever got an answer to the actual question, which was: It's true that you have never, when you consented a patient, told the patient that -- I understand that you tell them that the risk of erosion is generally around 2 percent, but you've never told a patient that in some studies, the risk of erosion can be as high as 19 percent; is that correct?

A It's not worth to even bring it up.

Q So the answer is yes; that's correct?

A I do not tell that to the patients.

Q Okay. So you've never done that?

A That would be misleading. I've not done that.

Q And you've never told -- in fact, it sounds like you were never aware that at one point Ethicon reported that 19 percent erosion on their website; correct?

A I am not aware.

MR. ROSENBLATT: Object to form.

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Q (By Mr. Faes) So, obviously, if you weren't even aware of it, that's not something you could have ever reported to a patient; right?

A I wasn't aware of that. And it's not a valuable information for the clinician or the scientist, it's an outlier.

Q So you made that decision yourself and decided that that wasn't information that needed to be passed on to your patients; right?

A Look, science -- science requires that you look at all the data, you then remove the outliers, you disregard them. You don't look at them any more, period.

Q Would you agree with me that if you were looking at having a medical device implanted, your decision-making process would be very different if you were told that there was a 2 percent chance of a serious adverse event versus a 19 percent chance; right?

A Correct, but it would be unfair to the patient to share that 19 percent information because it's an outlier. You are -- you're misleading her. So she's not -- she's not getting fair and honest counseling there. You're misleading her that 19 percent comes from, I don't know what, but probably that surgeon did only 10 TVTs. I don't even know that study, but I know in the hands of, let's say, beginner, yes, there are risks.

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Probably that surgeon published those results; that's what I would say. It would be unfair to the patient. If I tell 19 percent, I am making her not choose the right procedure, and that would be so wrong, unfair to the patient.

Q Do you think it would be a reasonable option to tell a patient that, as you said, you believe that there's a 2 percent risk of erosion with the TVT, and disclose the fact that there's been studies that showed it as high as 19 percent and explained to them that you think it's an outlier and let the patient make that decision for themselves?

A No, no, a scientist wouldn't do that. Scientist would see the problem with the methodology of the study and will say that this study is not worth even bringing to the discussion. That's what I do. If I went by every study I read in the literature, there would not be any decision being made anywhere because, again, literature is full of all kind of studies. If you pull one and make your decision based on that, everything I do is wrong. I don't do that, that would be so wrong.

Q So do you believe, as a physician, that you have an obligation to inform a patient considering a potential medical device or medical procedure like the TVT what the worst-case scenario is?

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A Okay. I mean, you don't start with the worst-case scenario first, okay. So if you start with worst-case scenario, no surgery would ever be done. So that would also be misleading. If any cardiac surgery, let's say you're discussing you'll die, start with that, guess whether -- like, see if that patient will stay in your office and will have this amazingly life saving procedure or not. So you're not going to say that.

So your physician -- your obligation as a physician is to put it out there as truly it is. If you don't do that, you're doing really a disservice to the patient and that's so wrong. If I put that 19 percent, which comes from one study when hundreds of studies here says it's 1 to 3, 2, maybe 4 percent, something like that, it would be so wrong; that patient will not choose the surgery which will change her life in an amazing way. She's going to exercise, lose weight. She can't now because she is losing urine. Do you know how bad it is?

Q So you feel it's your obligation as a doctor to filter this information and tell the patient what you think they need to know?

A Whatever word you're using you're using wrong words today. I can tell you that's not filtering. Look, it's analyzing the data, putting in the right perspective. It's my job as a scientist, as an academician to evaluate

everything available to me and then put it in the right context and present it to the patient. If I see that 19 percent, she has no clue where 19 percent came from, but I studied the methodology of that study and I will see that there are big flaws in that study. There's no way that study could represent the entire perioperative outcomes when 100 other studies performed by the top urogynecologists and followed prospectively, diligently, meticulously, they cannot have the same weight. Are you saying they have the same weight? Can I ask you questions, too?

Q No. Let me see if I can ask a follow up question here. So you're -- you don't think the best practice is to give the patient the information and let them make the decision themselves after explaining why you don't believe it's applicable; right?

A So we have pretty much 30 to 40 minutes to sit down with a patient when we are talking about the risks, benefits and all that. So obviously I must definitely absorb all the literature and put it in the right words to convey what this procedure is about. If I start talking about every procedure, there's like 5 -- I'm sorry, every study, there's probably 1,000 on TVT. And some are here at this end of the spectrum, some are at this end of the spectrum.

Maybe they're 100 percent effective procedures and there are people, like, who presented maybe zero complication rate; I'm not going to use either one of these two. Do you know what I'm going to use? As I've been saying, the bulk of the literature with the prospective level one evidence, if they all indicate one thing, which is 2 percent, that's what I'm going to share with my patient. If you do that, she's going to be confused, she won't understand it.

Q So you don't think that with -- example, with the TVT, that a patient has the right to know that there's a study out there that shows a 19 percent erosion rate; correct?

A If she wants to know every single study, if I have time, I will tell that. But I will also put it in the right context telling that this study has problems, and the majority of the studies done in the right hands found this. This is what you should go by. And that's my obligation to the patient. If I miss -- if I start with the 19 percent, which is very likely because of study flaws, that would be making the patient not choose the most appropriate option among my treatment management plans.

(Deposition adjourned: 5:01 p.m.)

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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

[WITNESS NAME] DATE

Subscribed and sworn to before me on this _____day of_____,20___, by _____ _____, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____

CERTIFICATION

STATE OF CONNECTICUT:
COUNTY OF HARTFORD:

I, SAMANTHA M. HOWELL, a Notary Public duly commissioned and qualified in and for the State of Connecticut, do hereby certify that pursuant to Mr. Faes there came before me on the 3rd of October, 2018, the following named person, to wit: Dr. Oz Harmanli, who was previously duly sworn to testify to the truth and nothing but the truth; that he was thereupon examined upon his oath; that the examination was reduced to writing by computer under my supervision and that this transcript is a true record of the testimony given by said witness.

I further certify that I am neither attorney nor counsel for, nor related to, nor employed by any of the parties to the action in which this deposition was taken, and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, or financially interested in the outcome of this action.

In witness whereof I have hereunto set my hand this 8th day of October, 2018.

_____
Samantha M. Howell
Notary Public

My Commission expires
September 31, 2021